UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

APOTEX INC. and APOTEX CORP.,

Plaintiffs,

-against-

ACORDA THERAPEUTICS, INC.,

Defendant.

11 Civ. 8803 (AT)

MEMORANDUM AND ORDER

ANALISA TORRES, District Judge:

In this action, Plaintiffs, Apotex Inc. and Apotex Corp., allege that Defendant, Acorda Therapeutics, Inc., made false and misleading promotional statements about its pharmaceutical product, Zanaflex capsules, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). Defendant moves for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. For the reasons stated below, Defendant's motion is GRANTED.

BACKGROUND

Zanaflex tablets and Zanaflex capsules are distinct pharmaceutical products approved by the Food and Drug Administration ("FDA") for the treatment of spasticity. Def. 56.1 ¶ 1, ECF No. 87; Pl. 56.1 ¶ 1, ECF No. 96. The active ingredient in both products is tizanidine. Def. 56.1 ¶ 1; Pl. 56.1 ¶ 1. One of the most common side effects associated with tizanidine is somnolence. Def. Mem. App. A at 3, ECF No. 86-1. Generic versions of Zanaflex tablets were introduced in the United States in 2002. Def. 56.1 ¶ 2; Pl. 56.1 ¶ 2. Plaintiffs began selling a generic version of the tablets in 2004. Def. 56.1 ¶ 2; Pl. 56.1 ¶ 2. In April 2005, Defendant began selling Zanaflex capsules. Def. 56.1 ¶ 3; Pl. 56.1 ¶ 3. The capsules had not been sold prior to April 2005. Def. 56.1 ¶ 3; Pl. 56.1 ¶ 3.

According to the FDA-approved "combined" product label for Zanaflex tablets and Zanaflex capsules (the "FDA label"), the products are not bioequivalent in the "fed state" (*i.e.*,

when administered with food). Def. 56.1 ¶ 5; Pl. 56.1 ¶ 5; *see also* Def. Mem. App. A at 1. The FDA label explains, among other things, that: "[f]ood has complex effects on tizanidine pharmacokinetics, which differ with the different formulations"; "[t]hese pharmacokinetic differences may result in clinically significant differences when . . . switching between the tablet and capsule in the fed state"; and "[t]hese changes may result in increased adverse events or delayed/more rapid onset of activity, depending upon the nature of the switch." Def 56.1 ¶ 10; Pl. 56.1 ¶ 10; *see also* Def. Mem. App. A at 4. The label also notes that "the prescriber should be thoroughly familiar with the changes in kinetics associated with these different conditions." Def. 56.1 ¶ 10; Pl. 56.1 ¶ 10; *see also* Def. Mem. App. A at 4.

On December 2, 2011, Plaintiffs filed the original complaint in this action. An amended complaint, filed on February 21, 2012, alleges that Defendant: (1) engaged in anticompetitive conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2; (2) made false and misleading promotional statements about Zanaflex capsules in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and N.Y. Gen. Bus. Law §§ 349, 350; (3) tortiously interfered with Plaintiffs' prospective business; and (4) was unjustly enriched by its purported misconduct. Am. Compl. ¶¶ 48-96, ECF No. 27. Defendant moved to dismiss the amended complaint. On February 7, 2013, the Honorable Laura Taylor Swain dismissed Plaintiffs' Sherman Act and state law causes of action—leaving only the Lanham Act claim remaining. ECF No. 45.

DISCUSSION

I. Standard of Review

Summary judgment is appropriate when the record shows that there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine dispute exists "if

the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Material facts are those which, under the governing law, may affect the outcome of a case. *Id.*

The moving party bears the initial burden of informing the court of the basis for its motion and identifying those portions of the pleadings, depositions, answers to interrogatories, admissions on file, and other materials in the record that demonstrate the absence of a genuine dispute. Fed. R. Civ. P. 56(a), (c); *Celotex*, 477 U.S. at 323. If the moving party meets its initial burden, the burden then shifts to the non-moving party to establish the presence of a genuine dispute. *Beard v. Banks*, 548 U.S. 521, 529 (2006); *Santos v. Murdock*, 243 F.3d 681, 683 (2d Cir. 2001). The moving party is entitled to judgment as a matter of law where the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof. *Celotex*, 477 U.S. at 322-23.

In ruling on a motion for summary judgment, all evidence must be viewed in the light most favorable to the non-moving party, *Overton v. N.Y. State Div. of Military & Naval Affairs*, 373 F.3d 83, 89 (2d Cir. 2004), and the court must "resolve all ambiguities and draw all permissible factual inferences in favor of the party against whom summary judgment is sought," *Sec. Ins. Co. of Hartford v. Old Dominion Freight Line, Inc.*, 391 F.3d 77, 83 (2d Cir. 2004). However, the non-moving party may not avoid summary judgment by "rely[ing] simply on conclusory statements." *Burt Rigid Box, Inc. v. Travelers Prop. Cas. Corp.*, 302 F.3d 83, 91 (2d Cir. 2002).

II. Section 43(a) of the Lanham Act

A. Applicable Law

Section 43(a) of the Lanham Act provides a cause of action against

> [a]ny person who . . . uses in commerce . . . any . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities.

15 U.S.C. § 1125(a)(1). To prevail on such a claim, the plaintiff must "show[] that the challenged advertisement is false and misleading, not merely that it is unsubstantiated by acceptable tests or other proof." *Procter & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) (citations omitted); *see also, e.g.*, *Mylan Pharm., Inc. v. Procter & Gamble Co.*, 443 F. Supp. 2d 453, 459 (S.D.N.Y. 2006) ("To establish a false advertising claim under section 43(a) of the Lanham Act, the [p]laintiff must demonstrate that the statement in the challenged advertisement is false."). Two theories are available to a plaintiff seeking to meet this burden. *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 153 (2d Cir. 2007). "First, the plaintiff can demonstrate that the challenged advertisement is literally false, *i.e.*, false on its face." *Id.* "[O]nly an *unambiguous* message can be literally false. Therefore, if the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false." *Id.* at 158 (internal quotation marks and citations omitted). "Alternatively, a plaintiff can show that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers." *Id.* at 153.

A plaintiff invoking the latter theory "must demonstrate, by extrinsic evidence, that the challenged [advertisement] tend[s] to mislead or confuse consumers." *Tiffany (NJ) Inc. v. eBay Inc.*, 600 F.3d 93, 112-13 (2d Cir. 2010) (internal quotation marks and citation omitted); *see also*

Time Warner Cable, 497 F.3d at 153 ("[A] district court *must* rely on extrinsic evidence [of consumer deception or confusion] to support a finding of an implicitly false message.") (alteration in original) (internal quotation marks and citation omitted). The plaintiff must produce such extrinsic evidence "even at the summary judgment stage." *Gameologist Grp., LLC v. Scientific Games Int'l, Inc.*, 838 F. Supp. 2d 141, 165 (S.D.N.Y. 2011), *aff'd*, 508 F. App'x 31 (2d Cir. 2013). Extrinsic evidence of consumer confusion ordinarily comes in the form of consumer surveys, "but this is not a hard-and-fast requirement." *Reed Constr. Data Inc. v. McGraw-Hill Cos., Inc.*, 09 Civ. 8578, 2014 WL 4746130, at *23 (S.D.N.Y. Sept. 24, 2014) (explaining that a plaintiff can show consumer confusion "using whatever evidence").

"In the context of pharmaceutical drugs, courts have generally rejected Lanham Act claims based on advertisements that merely repeat labeling information that has been approved by the FDA." *Mylan Pharm.*, 443 F. Supp. 2d at 460; *see also, e.g.*, *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (noting that promotional statements that "comport substantively with statements approved as accurate by the FDA cannot supply the basis for" a Lanham Act false advertising claim); *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987) (concluding that FDA approval of statements on a product label is "a defense to a competitor's action under the Lanham Act" and explaining that concerns as to the label's content are "to be addressed by the FDA and not by the courts in a Lanham Act suit"); *cf. Smithkline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 95 Civ. 7011, 1996 WL 280810, at *13 (S.D.N.Y. May 24, 1996) (suggesting that a district court should not "substitute [its] discretion for that of the FDA in approving package labelling for over-the-counter medications" by second-guessing the accuracy of those labels).

In addition to demonstrating falsity, "the plaintiff must . . . show that the defendant[] misrepresented an 'inherent quality or characteristic' of the product." *Nat'l Basketball Ass'n v. Motorola, Inc.*, 105 F.3d 841, 855 (2d Cir. 1997) (internal quotation marks and citation omitted). "This requirement is essentially one of materiality . . . ." *Id.* "[T]he Second Circuit has explained that satisfying this materiality requirement depends on whether the alleged inaccuracy in the statements at issue would influence the purchasing decisions of consumers." *Mylan Pharm.*, 443 F. Supp. 2d at 462 (citing *Nat'l Basketball Ass'n*, 105 F.3d at 855). "The plaintiff does not need to demonstrate that the defendant's representations actually affected consumer behavior, but rather only that they were likely to have done so." *Id.* at 463.

B. Allegedly False Statements and Images

To survive a motion for summary judgment, a plaintiff need not prove that challenged promotional statements *are* false. *E.g.*, *Merck Eprova AG v. Brookstone Pharm., LLC*, 09 Civ. 9684, 2011 WL 1142989, at *3 (S.D.N.Y. Mar. 17, 2011). However, the plaintiff must show that a reasonable juror *could* reach that conclusion. *See Anderson*, 477 U.S. at 248. In support of this burden, Plaintiffs point to the following statements and images:

- *Reduced Cmax – Sales Representatives' Statements*. Defendant's sales representatives told doctors that Cmax (*i.e.*, the maximum concentration of a drug in the blood after dosing) is reduced when Zanaflex capsules are taken with food. *See* Pl. Statement of Add'l Material Facts ("Pl. Supp. 56.1") ¶¶ 36-45, 49-52, 70, ECF No. 96; Def. Statement of Add'l Material Facts ("Def. Supp. 56.1") ¶¶ 36-45, 49-52, 70, ECF No. 99. Plaintiffs contend that this claim is false. Pl. Mem. 8, 11, ECF No. 95.

- *Reduced Somnolence – Sales Representatives' Statements*. Defendant's sales representatives told doctors that, when taken with food, Zanaflex capsules cause less somnolence than Zanaflex tablets. *See* Pl. Supp. 56.1 ¶¶ 36-45, 49-52; Def. Supp. 56.1 ¶¶ 36-45, 49-52. Plaintiffs contend that this claim is also false. Pl. Mem. 8, 11.

- *Reduced Cmax – Promotional Materials*. Defendant's promotional materials state that taking Zanaflex tablets with food increases Cmax by 30%, whereas taking Zanaflex capsules with food decreases Cmax by 20%. *See, e.g.*, Pl. Supp. 56.1 ¶ 74; Def. Supp. 56.1 ¶ 74. When this information appears in Defendant's promotional materials, it

typically accompanies a graph of mean tizanidine plasma concentration curves over time. *See, e.g.*, Pl. Supp. 56.1 ¶ 74; Def. Supp. 56.1 ¶ 74. Plaintiffs contend that the Cmax percentages are false and that the presentation of these percentages alongside the graph communicates a false and misleading message. Pl. Mem. 18-19.

- *Reduced Somnolence – Promotional Materials.* One of Defendant's promotional pieces—a "gatefold brochure"—includes the tagline "Flexible Control in a Capsule," images of the sun and moon, the words "day" and "night," and information about "Important Pharmacokinetic Differences." *See* Pl. Supp. 56.1 ¶¶ 83-84; Def. Supp. 56.1 ¶¶ 83-84. Plaintiffs contend that this brochure conveys the false and misleading message that taking Zanaflex capsules with food reduces somnolence. Pl. Mem. 22.

- *Pharmacokinetic Differences – Promotional Materials.* Defendant's promotional materials include statements about pharmacokinetic differences between Zanaflex capsules and tablets that differ from those featured on the FDA label, which, according to Plaintiffs, supports a falsity finding. Pl. Mem. 25-26.

The Court addresses each in turn, and concludes that Plaintiffs have failed to adduce sufficient evidence to survive a motion for summary judgment. Accordingly, Defendant is entitled to judgment as a matter of law. *See Celotex*, 477 U.S. at 322-23.

1. Reduced Cmax – Sales Representatives' Statements

Plaintiffs identify a number of instances in which Defendant's sales representatives told doctors that Cmax is reduced when Zanaflex capsules are taken with food. Pl. Mem. 8-11; *see also* Pl. Supp. 56.1 ¶¶ 36-45, 49-52. Defendant does not dispute that its sales representatives made these statements, Def. Supp. 56.1 ¶¶ 36-45, 49-52, but argues that the statements cannot give rise to liability under the Lanham Act because they are consistent with the FDA label. Def. Reply Mem. 1-4, ECF No. 100. The Court agrees with Defendant. The FDA label includes the following information about Cmax:

> When two 4 mg *tablets* are administered with food the mean maximal plasma concentration is increased by approximately 30% . . . . In contrast, when two 4 mg *capsules* are administered with food the mean maximal plasma concentration is decreased by 20% . . . . Consequently, the mean Cmax for the capsule when administered with food is approximately 2/3's the Cmax for the tablet when administered with food.

Def. Mem. App. A at 1 (emphasis added). Defendant's sales representatives' statements concerning Cmax are consistent with the product label. Accordingly, they cannot provide the basis for a Lanham Act false advertising claim. *See, e.g.*, *Mylan Pharm.*, 443 F. Supp. 2d at 460; *Cytyc Corp.*, 12 F. Supp. 2d at 301.

2. Reduced Somnolence – Sales Representatives' Statements

Plaintiffs also identify a number of instances in which Defendant's sales representatives told doctors that, when taken with food, Zanaflex capsules cause less somnolence than Zanaflex tablets. Pl. Mem. 8-11; *see also* Pl. Supp. 56.1 ¶¶ 36-45, 49-52. Again, Defendant does not dispute that its sales representatives made these statements, Def. Supp. 56.1 ¶¶ 36-45, 49-52, but argues that: (1) these statements were "unauthorized, isolated statements . . . [which] cannot give rise to false advertising liability," Def. Mem. 11, ECF No. 86; and (2) even if these statements could give rise to false advertising liability, Plaintiffs have failed to meet their burden of showing that a reasonable juror could find the statements to be false, *see id.* at 19-21. The Court rejects Defendant's first argument, but agrees with the second.

Defendant contends that the statements identified by Plaintiffs are merely "a few isolated statements that depart from company policy," which, according to Defendant, "do not constitute a Lanham Act violation" in the Second Circuit. *Id.* at 11. Defendant adds that "[s]uch statements are, by definition, not part of an organized campaign . . . which means they are not 'promotion' within the meaning of the Lanham Act." *Id.* (internal quotation marks omitted). In support of this proposition, Defendant cites *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48 (2d Cir. 2002). The Court disagrees with Defendant's reading of *Fashion Boutique*. In that case, the Second Circuit did not hold that "unauthorized, isolated statements by sales representatives" "are, by definition, not part of an organized campaign." Def. Mem. 11

(internal quotation marks omitted). Rather, the Second Circuit explained that "the touchstone of whether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market." *Fashion Boutique*, 314 F.3d at 57. Because there was "no evidence to suggest that [twenty-seven oral statements in a marketplace of thousands of customers] were part of an organized campaign to penetrate the marketplace," the Second Circuit concluded that the plaintiff had failed to show that the defendants' actions were "commercial advertising or promotion" under the Lanham Act. *Id.* at 58. Here, based on the evidence submitted, a reasonable juror could find that Defendant's sales representatives' statements were "part of an organized campaign to penetrate the relevant market." *Id.* at 57. Therefore, the Court cannot say as a matter of law that these statements do not constitute "commercial advertising or promotion."

In addition, Defendant argues that "courts will not impose liability where a pharmaceutical company defendant did 'not instruct' its sale[s] representatives to make allegedly false statements and where, after learning that such statements had been made, the company 'followed up with' its sales force 'and reinforced' company policy." Def. Mem. 12 (brackets and citation omitted). According to Defendant, "[t]he Lanham Act does not impose liability for such 'good faith efforts' at compliance." *Id.* (brackets and citation omitted). In support of these contentions, Defendant cites *Procter & Gamble Pharmaceuticals, Inc. v. Hoffmann-LaRoche Inc.*, 06 Civ. 0034, 2006 WL 2588002 (S.D.N.Y. Sept. 6, 2006). The Court does not read *Hoffmann-LaRoche* as broadly as Defendant. In that case, after conducting a four-day evidentiary hearing, considering oral argument, and reviewing the parties' proposed findings of fact and conclusions of law, the court denied the plaintiffs' motion for a preliminary injunction.

Id. at *1. In doing so, the court noted, among other things, that: (1) the evidence suggested that the defendant's sales representatives were not instructed to provide misinformation; (2) only two percent of the sales representatives' call notes supported the plaintiffs' claim; (3) the call notes were made by a "very small percentage of the overall sales force"; (4) "[t]hese representatives were spoken to and the appropriate messaging was reconfirmed"; and (5) the defendant "made a good faith effort to educate its work force" about the relevant data and "what could and could not be fairly said about it." *Id.* at *32. The court in *Hoffmann-LaRoche* did not hold that a plaintiff cannot, as a matter of law, establish a Lanham Act claim under the facts of this case. In any event, making such an assessment here would require the Court to weigh evidence and determine credibility, which the Court is not entitled to do in resolving a motion for summary judgment. *See Anderson*, 477 U.S. at 249. The Court, therefore, rejects Defendant's argument that the sales representatives' statements cannot, as a matter of law, give rise to false advertising liability under the Lanham Act.

This conclusion, however, does not mean that Plaintiffs have made a showing sufficient to survive a motion for summary judgment. Indeed, Plaintiffs must demonstrate that a reasonable juror could find the sales representatives' statements to be false. Plaintiffs contend that, to prove falsity, they need only show that the challenged statements are not supported by statistically significant evidence. Pl. Mem. 30-31. The Court disagrees. Plaintiffs appear to derive this standard from a line of cases involving advertising claims of "test-proven superiority." *Chesebrough-Pond's*, 747 F.2d at 116, 119 (challenged advertisement for New Wondra, a hand and body lotion, stated, *inter alia*: "[D]ermatologists proved it in clinical tests. New Wondra improves the condition of rough dry skin better[.]"); *see also Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 59 (2d Cir. 1992) (challenged commercial for Quaker State

10W-30 motor oil stated, *inter alia*: "[T]ests prove Quaker State 10W-30 protects better than any other leading 10W-30 motor oil."); *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1546 (2d Cir. 1991) (challenged advertisement for AF Excedrin, a pain reliever, stated, *inter alia*: "'[I]n doctor supervised clinical studies . . . AF Excedrin was shown to provide greater headache relief' than ES Tylenol.") (brackets omitted). In these cases, where a "defendant's ad explicitly or implicitly represents that tests or studies prove its product superior," the Second Circuit has held that a plaintiff can prove falsity "by showing that the tests did not establish the proposition for which they were cited." *Castrol*, 977 F.2d at 63; *see also, e.g.*, *Glaxo Warner-Lambert OTC G.P. v. Johnson & Johnson Merck Consumer Pharm. Co.*, 935 F. Supp. 327, 329 (S.D.N.Y. 1996) (explaining that this "less stringent standard" applies where promotional claims "mention 'studies' or 'tests,' or make statements while pointing to graphs or similar items"). "[A] plaintiff can meet this burden by demonstrating that the tests were not sufficiently reliable to permit a conclusion that the product is superior." *Castrol*, 977 F.2d at 63. On the other hand, where a superiority claim makes no mention of tests or studies, a plaintiff must produce evidence affirmatively showing the claim to be false—*i.e.*, that the defendant's product is equal or inferior. *Id.* Likewise, where an advertisement does not make a superiority claim, a plaintiff must affirmatively prove the challenged statement to be false. *See, e.g.*, *Chesebrough-Pond's*, 747 F.2d at 119. Indeed, the plaintiff must do more than show that the statement is "unsubstantiated by acceptable tests or other proof." *Id.*

Here, none of the sales representatives' statements regarding somnolence involve claims of test-proven superiority. *Compare* Pl. Supp. 56.1 ¶¶ 36-45, 49-52, *with Chesebrough-Pond's*, 747 F.2d at 116, *Castrol, Inc.*, 977 F.2d at 59, *and McNeil-P.C.C., Inc.*, 938 F.2d at 1546. At most, the statements suggest that, due to pharmacokinetic differences between the products,

Zanaflex capsules cause less somnolence than Zanaflex tablets when taken with food. The statements do not, by contrast, "explicitly or implicitly represent[] that tests or studies prove" that there is less somnolence with Zanaflex capsules. *Castrol*, 977 F.2d at 63.[1] Accordingly, for the statements to give rise to liability under the Lanham Act, Plaintiffs must affirmatively prove them to be false.

Plaintiffs point to "a post-hoc analysis" of data from a single study "not designed or powered to detect differences in adverse events" (the "101 study"), which found no statistically significant difference between Zanaflex capsules and tablets with respect to adverse events such as somnolence. *See, e.g.*, Pl. Supp. 56.1 ¶¶ 60-67; Def. Supp. 56.1 ¶¶ 60-67. Based on this evidence, the Court concludes that no reasonable juror could find that Plaintiffs have affirmatively demonstrated that the sales representatives' statements were false. Plaintiffs' evidence merely shows the challenged statements to be "unsubstantiated by acceptable tests or other proof." *Chesebrough-Pond's*, 747 F.2d at 119. Plaintiffs cannot prove falsity by such evidence alone. *Id.* Therefore, to the extent that Plaintiffs' Lanham Act claim is based on Defendant's sales representatives' statements about somnolence, the claim cannot survive a motion for summary judgment.

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[1] The Court acknowledges that some of the challenged statements refer to a graph of pharmacokinetic differences between Zanaflex capsules and tablets, *see, e.g.*, Pl. Supp. 56.1 ¶ 38 ("I asked [the doctor] about the most common complaint with Zanaflex tablets and he said the drowsiness and then we went to the graph and I discussed the capsules . . . ."), but concludes that these statements do not constitute claims of test-proven superiority. Presumably, the graph cited by the sales representatives is the same one featured on the FDA label, Def. Mem. App. A at 1, and in Defendant's promotional materials, *see, e.g.*, Pl. Supp. 56.1 ¶ 74; Def. Supp. 56.1 ¶ 74, which shows mean tizanidine plasma concentration curves over time. Plaintiffs do not argue otherwise. Likewise, Plaintiffs do not suggest that Defendant's sales representatives told doctors that the graph shows levels of somnolence. At most, the evidence indicates that the sales representatives encouraged doctors to draw an inference not directly supported by the graph—which is insufficient to trigger the "less stringent standard," *Glaxo Warner-Lambert*, 935 F. Supp. at 329, for proving falsity.

3. Reduced Cmax – Promotional Materials

Turning to Defendant's promotional materials, Plaintiffs contend that these materials contain false and misleading information concerning Cmax. First, Plaintiffs argue that the promotional materials falsely state that taking Zanaflex tablets with food increases Cmax by 30%, whereas taking Zanaflex capsules with food decreases Cmax by 20%. Specifically, Plaintiffs assert that this information is false because: (1) "[t]he 101 study . . . reports the true Cmax increase is 22.6%"; and (2) the FDA label states that Cmax is increased by *approximately* 30% when Zanaflex tablets are administered with food. Pl. Mem. 18-19. The Court disagrees. As an initial matter, there is no indication in any of Defendant's promotional materials that the Cmax percentages are based on the 101 study. Plaintiffs' conclusory assertion that Defendant derived the numerical information from this source does not establish a genuine dispute. *See, e.g.*, *Burt Rigid Box*, 302 F.3d at 91. Instead, it is clear that Defendant drew the information from the FDA label, which, again, states:

> When two 4 mg *tablets* are administered with food the mean maximal plasma concentration is increased by approximately 30% . . . . In contrast, when two 4 mg *capsules* are administered with food the mean maximal plasma concentration is decreased by 20% . . . . Consequently, the mean Cmax for the capsule when administered with food is approximately 2/3's the Cmax for the tablet when administered with food.

Def. Mem. App. A at 1 (emphasis added). Because the Cmax numbers are consistent with the FDA label, they cannot provide the basis for a Lanham Act false advertising claim. *See, e.g.*, *Mylan Pharm.*, 443 F. Supp. 2d at 460; *Cytyc Corp.*, 12 F. Supp. 2d at 301. Furthermore, the omission of the word "approximately" before the 30% figure does not render the promotional claim false. The Cmax information included in Defendant's promotional materials is "similar enough to the [FDA-]approved statements for the Court to conclude, as a matter of law, that [it is] neither false nor misleading." *Cytyc Corp.*, 12 F. Supp. 2d at 301 (noting that promotional

statements need not "correspond precisely to statements that the FDA has approved" for the court to find that they are non-actionable under the Lanham Act).

Plaintiffs also argue that the presentation of the 20% and 30% Cmax figures alongside a graph of mean tizanidine plasma concentration curves over time, *see, e.g.*, Pl. Supp. 56.1 ¶ 74; Def. Supp. 56.1 ¶ 74, is false and misleading. Pl. Mem. 19. The Court finds that a reasonable juror could determine that the juxtaposition of this text and image communicates a literally false message. The pharmacokinetic curves on the graph show mean plasma tizanidine concentration (*i.e.*, the mean concentration of tizanidine in the blood), which is distinct from Cmax. Pl. Supp. 56.1 ¶¶ 69-70; Def. Supp. 56.1 ¶¶ 69-70; *see also* Miller Decl. Ex. 17 ("Jusko Report") ¶ 43, ECF No. 97-8. The parties agree that Cmax is "the highest level of tizanidine in the blood at whatever time that occurs." Pl. Supp. 56.1 ¶ 70; Def. Supp. 56.1 ¶ 70. According to Plaintiffs, because "each subject exhibits his or her own Cmax at different times following administration of the dosage form, and not necessarily at the time point showing the highest mean concentration for all subjects combined," Jusko Report ¶ 43, "one cannot simply look at the highest point on each curve and say that that is Cmax," Pl. Supp. 56.1 ¶ 71. Defendant's promotional materials indicate that the highest points on the "Tablets with Food" and "Capsules with Food" curves represent a "30% Increase for Tablets" and "20% Decrease for Capsules," respectively. *See, e.g.*, *id.* ¶ 74; Def. Supp. 56.1 ¶ 74. The unambiguous message of this graphic is that mean tizanidine plasma concentration increases by 30% when Zanaflex tablets are taken with food and decreases by 20% when Zanaflex capsules are taken with food. Plaintiffs have also submitted evidence that "[i]f one were to calculate the difference between the highest points on each of the four pharmacokinetic curves, there is only a 13% increase in [mean tizanidine plasma concentration] for the tablets and only a 12% decrease in [mean tizanidine plasma concentration]

for the capsules." Pl. Supp. 56.1 ¶ 81. In addition, Defendant acknowledges that the graph "does not include" the 20% and 30% Cmax figures. Def. Supp. 56.1 ¶ 69. Based on this evidence, a reasonable juror could find that the challenged graphic is literally false.

To prevail on a Lanham Act false advertising claim, however, a plaintiff must do more than prove falsity. The plaintiff must also show materiality, which requires evidence that "the alleged inaccuracy in the statements at issue would influence the purchasing decisions of consumers." *Mylan Pharm.*, 443 F. Supp. 2d at 462; *see also, e.g.*, *Medisim Ltd. v. BestMed LLC*, 910 F. Supp. 2d 591, 618 (S.D.N.Y. 2012) ("Even were [the defendant's] statement literally false, [the plaintiff] would still need evidence that it was *material*, *i.e.* that it was likely to influence purchasing decisions."). Here, Plaintiffs have offered no evidence that misstating the extent to which food affects mean tizanidine plasma concentration was likely to influence consumers' purchasing decisions. At most, Plaintiffs have submitted evidence indicating that Defendant overstated the increase in mean tizanidine plasma concentration for Zanaflex tablets by 17% and overstated the decrease in mean tizanidine plasma concentration for Zanaflex capsules by 8%. Such evidence does not reveal anything about the impact on consumers' purchasing decisions. Accordingly, because Plaintiffs have failed to make a sufficient showing of materiality, the Court finds that their claim regarding the mean tizanidine plasma concentration graph cannot survive a motion for summary judgment.

4. Reduced Somnolence – Promotional Materials

Plaintiffs identify a "gatefold brochure" for Zanaflex capsules as another example of Defendant's allegedly false advertising. *See* Pl. Supp. 56.1 ¶¶ 83-84, Def. Supp. 56.1 ¶¶ 83-84. Specifically, Plaintiffs assert that this brochure—with its tagline "Flexible Control in a Capsule," images of the sun and moon, the words "day" and "night," and information about "Important

Pharmacokinetic Differences"—"convey[s] to doctors that taking Zanaflex [c]apsules with food will lead to a reduction in Cmax and somnolence." Pl. Mem. 22.[2] Thus, according to Plaintiffs, "a trier of fact could readily conclude that this gatefold message is literally false and misleading." *Id.* The Court disagrees. Again, "only an *unambiguous* message can be literally false." *Time Warner Cable*, 497 F.3d at 158. "[I]f the language or graphic is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false." *Id.* Plaintiffs suggest that the brochure's only message is that administering Zanaflex capsules with food reduces somnolence. *See* Pl. Mem. 22. The Court finds that no reasonable juror could reach the same conclusion. Indeed, it is apparent that the brochure could be reasonably interpreted in a number of alternative ways (*e.g.*, Zanaflex capsules relieve symptoms throughout the entire day, Zanaflex capsules release the drug in a controlled manner, Zanaflex capsules allow for more effective treatment of spasticity over time). Therefore, Plaintiffs cannot prove the gatefold brochure to be literally false.

The Court likewise concludes that no reasonable juror could find that Plaintiffs have "show[n] that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers." *Time Warner Cable*, 497 F.3d at 153. To meet this burden, a plaintiff "must demonstrate, by extrinsic evidence, that the challenged [advertisement] tend[s] to mislead or confuse consumers." *Tiffany (NJ) Inc.*, 600 F.3d at 112-12 (internal quotation marks and citation omitted). The plaintiff must produce such extrinsic evidence "even at the summary judgment stage." *Gameologist Grp.*, 838 F. Supp. 2d at 165. Here, Plaintiffs have provided no extrinsic evidence of consumer confusion. Therefore, with respect to the alleged falsity of the

[2] Because the Court has already determined that Defendant's promotional claims about Cmax cannot give rise to liability under the Lanham Act, *see supra* Sections II.B.1, 3, the Court will not address Cmax again in this section.

gatefold brochure, Plaintiffs have failed to make a showing sufficient to survive a motion for summary judgment.

5. Pharmacokinetic Differences – Promotional Materials

Finally, Plaintiffs take issue with various statements in Defendant's promotional materials regarding pharmacokinetic differences between Zanaflex capsules and tablets. Specifically, Plaintiffs note that Defendant's promotional materials: (1) "state unequivocally that 'Effects and Adverse Events *are* Dose Related to Plasma Levels of Tizanidine,'" whereas the FDA label "say[s] only that effects *may* be dose-related to plasma levels"; (2) assert that "[s]ignificant pharmacokinetic changes including plasma level differences *occur* when administering Zanaflex [c]apsules[] or tablets with food," whereas the FDA label "say[s] only that pharmacokinetic differences *may* result in clinically significant differences"; and (3) "declare that 'Important Pharmacokinetic Differences Exist Between Zanaflex Capsules . . . and Tablets,'" whereas the FDA label "nowhere reflects the qualitative judgment that any differences between Zanaflex [c]apsules and tablets are 'important.'" Pl. Mem. 25-26.

A promotional claim is not literally false simply because it exaggerates an FDA-approved statement. Indeed, a plaintiff alleging falsity bears a greater burden—that is, the plaintiff must affirmatively prove that the promotional claim is false. *See, e.g.*, *Chesebrough-Pond's*, 747 F.2d at 119. Plaintiffs have presented no evidence that would support a reasonable juror's conclusion that: (1) effects and adverse events are *not* dose related to plasma levels of tizanidine; (2) significant pharmacokinetic changes do *not* occur when administering Zanaflex capsules or tablets with food; and (3) *no* important pharmacokinetic differences exist between Zanaflex capsules and tablets. Likewise, to the extent that Plaintiffs suggest that these statements are misleading, they have provided no extrinsic evidence of consumer confusion. Moreover, even if

Plaintiffs had offered such evidence, no reasonable juror could find for Plaintiffs because they have produced no evidence that the alleged inaccuracies were likely to influence consumers' purchasing decisions. *See, e.g.*, *Medisim Ltd.*, 910 F. Supp. 2d at 618. Accordingly, Plaintiffs' Lanham Act claim fails.

CONCLUSION

For the reasons stated above, Defendant's motion for summary judgment is GRANTED.[3] The Clerk of Court is directed to terminate the motion at ECF No. 85 and to close the case.

SO ORDERED.

Dated: October 23, 2014
New York, New York

ANALISA TORRES
United States District Judge

[3] Because Plaintiffs' failure to make a sufficient showing on essential elements of their case entitles Defendant to judgment as a matter of law, the Court need not address Defendant's arguments regarding Plaintiffs' claim for damages. *See* Def. Mem. 21-25.